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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,391	12/22/2003	Timothy Raymond Hirst	00833-P0043A	7178

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EXAMINER

DOWELL, PAUL THOMAS

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,391	HIRST, TIMOTHY RAYMOND	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-21, 23-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-21, 23-25 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, 21, 23-25, drawn to a method of delivering an agent to a cell comprising contacting said cell with a composition comprising said agent and either a mutant form of *E. coli* heat labile enterotoxin B subunit (EtxB) or a mutant form of *Vibrio cholerae* cholera toxin B subunit (CtxB); wherein said mutant form of EtxB or mutant form of CtxB has GM-1 binding activity but has reduced immunogenic and immunomodulatory activity relative to the wild type form of EtxB or CtxB; wherein said agent is selected from the group consisting of a peptide/protein, an antigen, an antigenic determinant, an antibody and a nucleic acid; wherein said antigen is selected from the group consisting of a viral antigen, a bacterial antigen, a parasitic antigen and a tumor associated antigen; and a kit comprising said mutant form of EtxB or CtxB and an agent, classified in class 514, subclass 2.
- II. Claims 19, 20, drawn to a composition comprising either a mutant form of EtxB or a mutant form of CtxB; wherein said mutant form of EtxB or mutant form of CtxB has GM-1 binding activity but has reduced

immunogenic and immunomodulatory activity relative to the wild type form of EtxB or CtxB, classified in class 530, subclass 350.

While the inventions of groups I and II are related in being drawn to mutant forms of EtxB or CtxB, they are patentably distinct because the composition of group II is not drawn to an agent to be delivered to a cell while group I is drawn to a method of delivering an agent to a cell. Thus, the composition of group II cannot be used in the method of group I. Therefore, the inventions of the groups I and II are patentably distinct each from the other and will require separate and non-coextensive searches in the patent and non-patent literature.

Further, Applicant is required to elect either a mutant form of EtxB or a mutant form of CtxB. This election requirement applies to claims 1, 12, 14, 15, 17, 19 and 21 and must be made upon election of group I or group II. It is noted that this is not a species election since EtxB and CtxB are distinct proteins and have distinct structure and function.

Further, Applicant is required to elect one agent from the group consisting of a peptide/protein, an antigen, an antigenic determinant, an antibody and a nucleic acid. This election requirement applies to claims 2, 13 and 21 and must be made upon election of group I. It is noted that this is not a species election since peptide/protein, an antigen, an antigenic determinant, an antibody and a nucleic acid have distinct structure and function. Still further, if Applicant elects "an antigen" from the group of agents listed

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above upon election of group I, Applicant is further required to elect one antigen selected from the group consisting of a viral antigen, a bacterial antigen, a parasitic antigen and a tumor associated antigen. It is noted that this is not a species election since a viral antigen, a bacterial antigen, a parasitic antigen and a tumor associated antigen have distinct structure and function.

Because these inventions of groups I and II are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and divergent classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be completed must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Dowell
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Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER